

USC 112, second paragraph appearing at the bottom of page 3 of the Official Action.

New claims 18-22 have been added more completely to define the subject matter which Applicants regard as their invention. These claims draw clear support from the specification as filed. All claims presently of record are believed to be sufficiently definite to satisfy the dictates of 35 USC 112, second paragraph.

The claims stand rejected under 35 USC 112, first paragraph, because the specification is allegedly not enabling for the transformation and regeneration of seeds (other than barley plant seeds) expressing the product of one or more of the recited enzymes. Applicants respectfully traverse this rejection.

The test of enablement is whether one reasonably skilled in the art could make or use the invention from the Applicants' disclosure coupled with information known in the art without undue experimentation. The fact that experimentation may be required, or that the experimentation may be complex, does not necessarily make it undue, if the art typically engages in such experimentation (see MPEP Section 2164.01). Factors to be considered in determining whether any necessary experimentation is "undue" include: (A) The breadth of the claims; (B) The nature of the invention; (C) The state of the prior art; (D) The level of one of ordinary skill; (E) The level of predictability in the art; (F) The amount of direction provided by the inventor; (G) The existence of working examples; and (H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure (see MPEP Section 2164.01(a)). In the present case, an analysis of the

relevant factors shows that any experimentation that would be needed to practice the invention as claimed would not be "undue".

The Nature of the Invention

The claimed invention is directed to a process for preparing an alcoholic beverage wherein the process is patentable over the prior art by virtue, for example, of the selection of the mixture of enzymes that is used to prepare the alcoholic beverage. As discussed in the present specification, Applicants have surprisingly found that the brewing process can be performed in the presence of the mixture of enzymes as claimed with a minimal amount of malt. The novelty and nonobviousness of this feature of the claimed invention is shown by the issuance of US Patent 6,361,808 from the parent application.

In contrast, as acknowledged in the specification, and as discussed further below, the general use of transgenic seeds containing an enhanced amount of enzyme in industrial enzyme-catalyzed processes is known in the prior art. In other words, the novelty or nature of the claimed invention does not pertain to the use of transgenic seeds containing such enzymes per se. As discussed below, this information is known in the prior art and the particulars as to the plants and enzymes used in the claimed should not preclude Applicants from obtaining broad protection of the invention.

The Existence of Working Examples

The present specification contains working examples of the invention as claimed, and includes working examples using Malt Seed comprising the recited enzymes.

Amount of Direction Provided

Production of barley seeds transformed with one or more recombinant enzyme genes of endo- β (1,4) xylianase, arabinofuranosidase, alpha-amylase, endo-protease or a β -(1,3: 1,4)-glucanase, is given in the present specification for illustrative purposes, and for illustrative purposes only. Examples of plant genera capable of producing enzymes of interest in their seeds are detailed in the specification (page 7, lines 9-22). The genes encoding the above enzymes of the claimed invention are readily available to a person skilled in the art (see specification at page 4, line 27-page 5, line 19). Methods of incorporation of a gene(s) of interest, transformation and regeneration techniques (in a wide range of plants) are detailed in the specification (page 7-page 13, line 26). Thus a process within the scope of claims 9-17 could be readily carried out by a person skilled in the art by following the teachings as provided in the specification, together with consideration of known techniques, all without necessitating undue experimentation.

Level of Predictability in the Art

Applicant respectfully disagree with the Examiner's comments that the "production of any random plant host and the production of seeds therefrom" were not within the recognized level of skill in the art at the time of the invention, and that the field of production of transgenic plants is "highly unpredictable" and problematical.

Transformation is reported at pages 10-11 of the specification to be routine in a number plant species (both *Monocotyledonae* and *Dicotyledonae*.) Examples of plant genera capable of producing enzymes of interest in their seeds are detailed in the specification (page 7, lines 9-22). Also, the specification details several means for obtaining transgenic plants capable of constitutively expressing more than one chimeric gene (see specification at pages 12-13). It is clear, as detailed throughout the specification, that various molecular biological techniques to obtain seeds encompassed by the claims were known to persons skilled in the art. So, taking into consideration the information provided in the specification, together with information available to a person skilled in the art at the time, there would be no reason why a person skilled in the art would not be able to express one or more of the claimed enzymes in plants other than barley using routine experimentation.

Level of One of Ordinary Skill

Applicant's respectfully draw the Examiner's attention to the following documents, most of which were published before 5 August 1996 (the earliest claimed priority date for the above application) and which provide evidence concerning the level of skill at the time the invention was made. WO 96/04392, in the name of Pioneer Hi-Bred International, was published on 15 February 1996 and describes

transformation of cereals; WO 96/22015 (University of Melbourne) was published on 25 July 1996 and describes the transformation of grasses; US 5,550,318 (DeKalb Genetics Corporation) was published on 27 August 1996 and describes the transformation of monocots; US 5,589,617 (National Research Council of Canada) was published on 31 December 1996 and describes the transformation of monocots; EP 0672 752 (Japan Tobacco Inc.) was published on 29 September 1995 and describes the transformation of monocots; US 5,464,765 (Zeneca Limited) was published on 7 November 1995 and describes the transformation of plants cells; WO 95/06127 was published on 2 March 1995 and describes the transformation of cereals; WO 95/06128 (DeKalb Genetic Corporation) was published on 2 March 1995 and describes the transformation of maize and WO 94/13822 (Ciba-Geigy AG) was published on 23 June 1994 and describes the transformation of wheat.

Applicants also respectfully draw the Examiner's attention to US patent 5,714,474 (Gist-Brocades) with a priority date of 25-3-91 (well before the priority date of the above application) which describes the production of enzymes in seeds. Example 8, herein describes the stable seed-specific expression of phytase in tobacco seeds; Example 15 of the same document describes the stable expression of alpha-amylase in tobacco. This teaching along with the above cited (patent) literature, confirms that a person skilled in the art would not have to experiment unduly to implement a process as claimed.

State of the Art

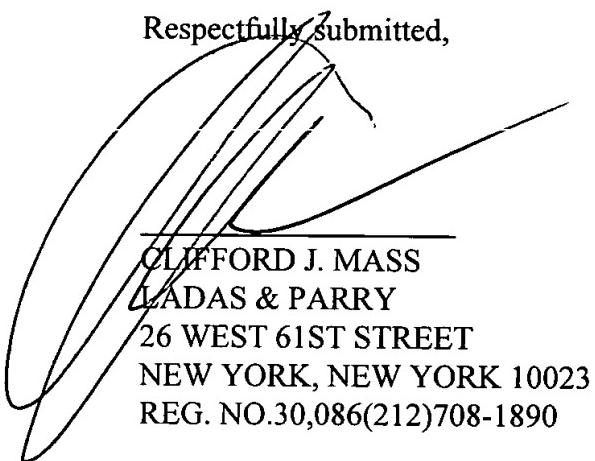
Applicants respectfully disagree with the Examiner's comments that "no source of the enzyme genes is provided" for claims 15-17. Genes encoding the recited enzymes of the claimed invention are readily available to a person skilled in the art, as discussed in the specification at page 4, line 27-page 5, line 19. Additionally as disclosed in the specification at page 7, lines 18-to page 10, line 25, methods were known in the art at the time to provide tissue specific expression of prokaryote genes in eukaryotic hosts. So again taking into consideration the information provided in the specification, together with information available to a person skilled in the art at the time, there would be no reason why a person skilled in the art could not routinely (i.e., without undue experimentation) conduct the steps of:

- a) expressing a prokaryote genes in seeds of a eukaryote host and
- b) using transgenic seed expressing the enzymes endo- β (1,4) xylanase, arabinofuranosidase, alpha-amylase, endo-protease or β -(1,3; 1,4) -glucanase of the invention, from plants such as barley, hops and wheat and others in the process as claimed.

In short, production of barley seeds (transformed with recombinant genes encoding the recited enzymes) is given as an example only. It is clear from the specification that application of the invention is not limited only to barley seed. Furthermore, as shown by an analysis of relevant factors (see above), there is no reason why a person skilled in the art could not practice the invention as claimed without undue experimentation in plants other than barley.

In view of the above, it is respectfully submitted that a person of skill in the art could practice the invention as claimed herein without undue experimentation such that the specification is enabling for the invention as claimed. Accordingly, it is respectfully believed that the rejection under 35 USC 112, first paragraph, should be withdrawn and that the application is in allowable form. An early notice of allowance is earnestly solicited and is believed to be fully warranted.

Respectfully submitted,



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Claim 9 (amended) In a process for preparing an alcoholic beverage comprising heating, steeping or mixing a plurality of raw materials to form a brew, the improvement comprising adding to the brew during any stage of its formation a non-malt component or a plurality of non-malt components collectively comprising a mixture of enzymes including at least an endo β -(1,4)-xylanase[s], an arabinofuranosidase, an alpha-amylase, an endo-protease and a β -(1,3-1,4)-glucanase, wherein the enzymes are present in respective amounts sufficient to provide the alcoholic beverage with a taste profile of a malt brew having a higher malt content than said alcoholic beverage, and wherein the component or plurality of components [comprise a] is present in seed.

Claim 10 (amended) A process according to claim 9, wherein the seed is from a transgenic plant line, said [that sets] seed containing at least one of said enzymes.

Claim 11 (amended) A process according to claim 9, wherein [a] the plurality of the components collectively comprising said mixture of enzymes is added to the brew, each of said plurality of components being present in the [comprising a] seed, said seed comprising a plurality of individual seeds with each individual seed containing a respective one of said enzymes such that each of the enzymes is included in the beverage from a seed component.

Claim 12 (amended) A process according to claim 11, wherein each of the individual

[respective] seeds [containing said components] is from a different transgenic plant line, each of the different transgenic plant lines [setting] providing seed containing a respective one of said enzymes.

Claim 14 (amended) A process according to claim 13, wherein the seed is from a transgenic plant line that [sets] produces seed containing said plurality of enzymes.